## REMARKS

Status of the Claims

*Pending claims*

Claims 36 to 54 are pending and under examination. Claims 37, 39, 41-42, 45, 47, 50 and 52-54 have been withdrawn from consideration leaving claims 36, 38, 40, 43, 44, 46, 48, 49 and 51 under examination in the instant Office Action.

*Claims amended, canceled and added in the instant amendment*

Claims 46, 48 and 49 are amended and claims 36, 38, 40, 43, 44 and 51 are canceled, without prejudice. Thus, after entry of the instant amendment, claims 46, 48, and 49 will be pending.

Support for the Claim Amendments

The specification sets forth an extensive description of the invention in the amended claims. Support for claims directed to a method involving the transient disruption of myelin or demyelination in human neurological tissue can be found, inter alia, on page 27, line 13.

Applicants respectfully request entry of the amendments set forth in this response under 37 CFR §1.116. The amendment does not raise any issues of new matter and the amended claims do not present new issues requiring further consideration or search.

Priority

Applicant had previously claimed priority at the time of the National Stage filing of this application and further has amended the priority information on page one of the application, thereby rendering this rejection moot.

Drawings

The Examiner has requested correction of the informalities indicated in the "Notice of Draftperson's Patent Drawing Review", PTO-948. A clearer copy of the drawings, Figures 1-10, is submitted to address this issue.

Specification

An abstract on a separate sheet is submitted herewith as required by 37 CFR 1.72(b).

Claim Objections

The Examiner objects to claim 43 for failing to end with a period. Claim 43 has been canceled and does not appear in the amended claims.

Rejections under 35 USC §101

The Examiner rejects claim 36 under 35 U.S.C. §101 alleging that the claimed invention lacks patentable utility. In the instant amendment claim 36 is canceled.

Rejections under 35 USC §112, first paragraph

The Examiner rejects claims 36, 38, 43, 44, 46, and 48 under 35 U.S.C. §112, first paragraph, alleging that the specification does not enable a person skilled in the art to practice the invention commensurate in scope with these claims. In particular, the Examiner alleges that the instant specification does not enable the practice of the claimed method in any mammalian subject other than the rodent model exemplified in the specification. Applicants respectfully disagree with the Examiner's rejection.

Applicant has cancelled claims 36, 38, 43, 44 and 51, without prejudice and has amended claim 46 to further clarify the subject matter of the invention. After entry of the instant amendment, the claims are directed to a method involving the transient disruption of myelin in human neurological tissue as supported throughout the specification, for example, at page 27, line 13.

Applicants respectfully disagree with the Examiner's position that the Specification is not enabled for use of the claimed method in any mammalian subject other than the rodent model exemplified in the specification.

Applicants respectfully traverse the foregoing rejection on the grounds that the claimed invention is fully enabled by the disclosure in Applicant's specification. Applicants submit that the Examiner's position, in effect, imposes an additional requirement, one not contained in 35 U.S.C. §112, of a working example or examples to enable the breadth of the claims directed to the claimed methods. Applicants assert that a working example is not required to enable the breadth of the pending claims and that "there is no magical relation between the number of representative examples and the breadth of the claims". In re Borkowski and VanVenroy, 164 U.S.P.Q. 642, 646 (C.C.P.A. 1970). In fact, § 112 only requires that the "specification contain a written description of the invention, and the manner and process of making and using it".

Additionally, it is well settled that the disclosure of invention set forth by Applicants in their application must be given the presumption of correctness and operativeness by the PTO, and the only relevant concern of the PTO under the circumstances should concern the truth of the assertions contained in the application. In re Marzocchi, 439 F.2d 220, 169 U.S.P.Q. 367 (C.C.P.A. 1967); see also, In re Bowen, 492 F.2d 859, 181 U.S.P.Q. 48 (C.C.P.A. 1974). The Examiner fails to proffer any evidence to controvert the truth of Applicants' assertions in the instant specification.

The Examiner bases the rejection on the assertion that the specification fails to provide any guidance on how to practice the method and therefore would require undue experimentation by a person skilled in the art. Applicants respectfully point out to the Examiner the teaching found, for example, at: pages 18-24 where the generation of antibodies for use in a human subject is described; pages 24-26 where the complement proteins or fragments for use in the invention are described; and pages 28-30 where teaching on the route, duration, and quantity for administration of this immunological activating composition is provided. In view of the teaching provided in the instant specification, it is asserted that the claimed method, as defined by the amended claims, would not require undue experimentation by the person skilled in the art and is,

therefore, sufficiently enabled. Accordingly, Applicants respectfully request that the section 112 rejection be withdrawn.

The Examiner also rejects claims 40, 49, and 51 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to practice the invention. In particular, the Examiner alleges that the instant specification does not enable the treatment of all or any dysfunctions of the nervous system. Applicants traverse the Examiner's rejection based on the following amendments and reasons.

After entry of the instant amendment, claims 40 and 51 are canceled and claim 49 depends from claim 46 to recite a method for promoting neuron repair or regeneration in a human subject having a nervous system dysfunction.

Applicants assert that the specification sufficiently enables the claimed method for promoting neuron repair or regeneration in a human subject, for the same reasons as indicated above. The specification further describes the application of the claimed method in subjects having a nervous system dysfunction, for example at page 18, line 1, and page 27, lines 14-19. Accordingly, Applicants assert that amended claim 49 is fully enabled and respectfully request that the section 112 rejection be withdrawn.

Rejections under 35 USC §112, second paragraph

The Examiner rejects claims 36, 38, 40, 43, 44, 46, 48, 49, and 51 under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, the Examiner rejects claims 36, 43, 46, 48, 49, and 51 alleging that these claims are indefinite for being incomplete for omitting essential steps. The Examiner has asserted that the omitted steps are: the step that indicates the induction of myelin disruption (claims 36 and 43), neuron regeneration (claims 46 and 48), and treatment of nervous system dysfunction (claims 49 and 51).

In making this rejection, the Examiner has referred to MPEP § 2172.01. It is our understanding that this rejection requires that the unclaimed matter must be described in the specification as being essential to the invention. Applicants respectfully point out to the

Examiner that the instant invention relates to a method that involves the transient disruption of myelin and the resulting promotion of neuron repair. To promote neuron regeneration, in accordance with the invention, it is not necessary to carry out an indicating step as suggested by the Examiner. Moreover, nowhere is it described in the specification that the step of indicating regeneration is necessary to practice the invention. Accordingly, Applicants respectfully request withdrawal of this section 112 rejection.

*The phrase "an immunological activating agent"*

The Examiner rejects claim 36 as being indefinite and ambiguous for recitation of "an immunological activating agent". In the instant amendment claim 36 is canceled.

*The statement "and/or"*

The Examiner rejects claims 36 and 46 as being indefinite for the "and/or" statements. The claims have been amended to replace the "and/or" term with the term "or" as suggested by the Examiner.

*The phrase "therapeutically effective amounts"*

The Examiner rejects claims 43 and 46 as being vague and indefinite for reciting "therapeutically effective amounts". In particular, the Examiner alleges that it cannot be determined from the instant specification the meaning of "therapeutically effective amounts". Applicants respectfully draw the Examiner's attention to the teaching on page 28, lines 5-12, where the term "therapeutically effective amount" is defined as "an amount of composition sufficient to effectively and transiently disrupt and /or demyelinate the CNS so that repair and regeneration of neurological tissue and neuronal connections is enhanced". Furthermore, in one embodiment, the range of the components of the composition (i.e., antibody and complement) are provided at lines 8-12 of the same page. Accordingly, the term "therapeutically effective amount" is in reference to the composition comprising the combination of antibody and complement. The claims will reflect this definition after entry of the instant amendment.

*The phrase "demyelination of myelin"*

The Examiner rejects claims 46 and 49 as being vague and ambiguous for recitation of the phrase "demyelination of myelin". After entry of the instant amendment, the claims will recite "disruption of myelin or demyelination" for purposes of clarity.

Rejections under 35 USC §102(b)

The Examiner rejects claims 36, 38, 40, 43, 46, and 49 under 35 U.S.C. 102(b) as being anticipated by Dyer et al. (1995, Society of Neuroscience Abstracts). Dyer et al. describe the disruption of myelin in chick and mouse neuronal tissue after intraspinal injection of serum complement proteins and myelin specific antibodies. The observations made by Dyer et al., however, were limited to treatment in undamaged neuronal tissue (i.e., neuronal tissue that does not comprise lesions). Accordingly, Dyer et al. do not teach the regeneration or repair of damaged neuronal tissue resulting from the disruption of myelin. Accordingly, Applicants assert that the amended claims are novel over Dyer et al. and respectfully request withdrawal of the 102(b) rejection.

The Examiner also rejects claim 46 under 35 U.S.C. 102(b) as allegedly anticipated by Keirstead et al. (1992). Keirstead et al. describe the neuroanatomical repair of embryonic chicken spinal cord occurring after the delay of the normal onset of myelination during the developmental period of the embryonic chicken (i.e., dysmyelination). To delay the onset of myelination in the embryonic chicken spinal cord, Keirstead et al. teach the use of an IgG3 mouse GalC antibody plus 20% homologous serum (as a source of complement). Keirstead et al., however, do not teach the transient disruption of already-existing myelin. Moreover, Keirstead et al. do not teach the neuroanatomical repair and functional recovery in a mammalian subject as recited in the amended claim. Accordingly, Applicant asserts that amended claim 46 is novel over Keirstead et al and request withdrawal of the rejection.

## CONCLUSION

In view of the foregoing amendment and remarks, it is believed that the Examiner should withdraw the rejection of the pending claims. Applicants believe all claims pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

A check in the amount of $460.00 is enclosed for the three month Extension of Time fee. The Commissioner is hereby authorized to charge any other fees that may be associated with this communication, or credit any overpayment to Deposit Account No. 50-1355. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

In the Claims:

Claims 36, 38, 40, 43, 44 and 51, have been canceled, without prejudice. The claims have been amended as follows:

46. (Once amended) A method for promoting neuron repair [and/]or regeneration in a human subject by the transient disruption of myelin [and/]or transient demyelination [of myelin], comprising [administration] administering [of] a therapeutically effective amount[s] of [the following] a composition comprising:

(a) one or more complement-fixing antibodies or fragments thereof, which specifically bind to an epitope of myelin; and
(b) one or more complement proteins or fragments thereof;

wherein the combination of said antibodies and complement proteins causes disruption of myelin [and/]or demyelination [of myelin], thereby promoting neuron repair or regeneration.

48. (Once amended) The method of claim [11] 46, wherein the complement proteins or fragments thereof include a C3 fragment, variant, analog, or chemical derivative thereof.

49. (Once amended) The method of claim 46, wherein the subject has a nervous system dysfunction.

In the Specification:

On page 1, prior to "Field of the Invention", please insert the following:

This application claims priority to application PCT/CA98/00997, filed October 28, 1998, under 35 U.S.C. 371, which claims priority under 35 U.S.C. 119 to application CA 2,251,410, filed October 16, 1998 and CA 2,219,683, filed October 28, 1997, all of which are herein incorporated by reference.